EU DECLARATION OF CONFORMITY (DoC)

<table>
<tr><td>Manufacturer:</td><td>Becton, Dickinson and Company
7 Loveton Circle
Sparks, Maryland 21152, USA</td></tr>
<tr><td>Manufacturer SRN:</td><td>US-MF-000018910</td></tr>
<tr><td>Authorised Representative:</td><td>Becton Dickinson Ireland Ltd.
Donore Road, Drogheda Co. Louth,
A92 YW26, Ireland</td></tr>
<tr><td>Authorised Representative SRN:</td><td>IE-AR-000007610</td></tr>
<tr><td>Product:</td><td>
<table>
<tr><th>Catalog Number</th><th>Product Trade Name</th></tr>
<tr><td>448010</td><td>BD Phoenix™ AP</td></tr>
<tr><td>448017</td><td>BD Phoenix™ AP Inoculation Station</td></tr>
<tr><td>448034</td><td>BD Phoenix™ AP system software</td></tr>
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</td></tr>
<tr><td>Basic UDI-DI:</td><td>
<table>
<tr><th>Catalog Number</th><th>Product Trade Name</th><th>Basic UDI-DI</th></tr>
<tr><td>448010</td><td>BD Phoenix™ AP</td><td>038290CVTXXFEGLY</td></tr>
<tr><td>448017</td><td>BD Phoenix™ AP Inoculation Station</td><td>038290CXIZSJWHKJ</td></tr>
<tr><td>448034</td><td>BD Phoenix™ AP system software</td><td>038290DGBEHUFHWN</td></tr>
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</td></tr>
<tr><td>Risk Class and Rule:</td><td>Class A, Rule 5(b), Rule 1.4</td></tr>
<tr><td>Intended Purpose:</td><td>
<table>
<tr><th>Catalog Number</th><th>Product Trade Name</th><th>Intended Purpose</th></tr>
<tr><td>448010</td><td>BD Phoenix™ AP</td><td rowspan="3">The BD Phoenix AP instrument is designed for use with the BD Phoenix system. It is intended to standardize ID broth tube inoculum, add AST indicator to the AST broth tube and transfer an aliquot of ID broth to AST broth tubes, as required for preparing samples for use on the BD Phoenix system, which performs identification and susceptibility testing.</td></tr>
<tr><td>448017</td><td>BD Phoenix™ AP Inoculation Station</td></tr>
<tr><td>448034</td><td>BD Phoenix™ AP system software</td></tr>
</table>
</td></tr>
<tr><td>Notified Body:</td><td>Not applicable, device self-certified</td></tr>
</table>

We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above-mentioned product(s) meet(s) the provisions of the following Directives/ Regulation(s):

- Regulation (EU) 2017/746 on *In vitro* Diagnostic Medical Devices.
- Directive 2011/65/EU as amended (EU) 2015/863 on Restriction of the use of certain hazardous substances in electrical and electronic equipment as amended by Commission Delegated Directive 2015/863 (RoHS)

Conformity Assessment Route:

☐ ANNEX IX Technical File Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☐ ANNEX IX Full Quality System	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☐ ANNEX X Type Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☐ ANNEX XI Production Quality System	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☒ ANNEX I & II+III	N/A

Common Specifications (CS):

Number:	Title:	Full or Partial Application:

Common Specification have not been issued for this product.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
448010	BD Phoenix™ AP	Class A
448017	BD Phoenix™ AP Inoculation Station [a]	Class A
448034	BD Phoenix™ AP system software [a]	Class A

[a] Product is not in scope for RoHS Directive 2011/65/EU

Authorised Signatory:	
Name & Title:	Anne Zavertnik, Vice President, Regulatory Affairs
On behalf of:	Becton, Dickinson and Company
Place of Issue:	Sparks, MD, USA
Date of Issue:	10-Nov-2022
Signature:	DocuSigned by: Anne Zavertnik Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 | 11:33:09 PM GMT DC6A638A32E64A8A91F9D8DE330F0415

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release
02	Revision 04 Template change. updated details in Product, Basic UDI-DI and Intended Purpose to tabular format. removed not available from common specifications table and formatting changes were made.